REMARKS

Claims 1-17 and 19-28 are pending in the application. Claim 18 has been cancelled and its subject matter has been added to Claim 1. Claims 4-17, 20, 24 and 26 are currently withdrawn pursuant to a restriction requirement. Thus, Claims 1-3, 19, 21-23, 25, 27 and 28 are presently under examination. Claims 1-17 and 19-26 have been amended. New Claims 27-28 have been added. Claim 1 has been amended to add further description; support for this amendment may be found in the specification and Claims as filed, for example, Claim 18. Claims 2-17 and 19-26 have been amended to add slight wording changes and to conform those claims to amended Claim 1. New Claims 27 and 28 have been added to describe more particular embodiments of the invention; support for these claims may be found in the specification, for example, page 6, paragraph 29 and pages 11-12, paragraph 42. No new matter has been added by any of the changes. Thus, Claims 1-3, 19, 21-23, 25, 27 and 28 are presently under examination.

Clarification of Errors on Cover Sheet of Office Action

It appears as if the Examiner used incorrect information on the cover sheet of the Office Action. It is noted that this Office Action is not final and that the Office Action is in response to an Amendment and Response filed by Applicant's attorney on September 12, 2008, not December 5, 2007.

Rejection Under 35 U.S.C. § 112, first paragraph

Applicant's attorney acknowledges with thanks the withdrawal of the rejection under 35 USC §112.

Rejection Under 35 U.S.C. § 102(a)

In the Office Action, the Examiner rejected Claims 1, 2, 17-19, 21-23 and 25 as being anticipated by Weber (WO 2003/026532) ("WEBER"). This rejection is respectfully traversed.

The present device of independent Claim 1, as amended, is directed to

An implantable or insertable medical device comprising a release region, said release region comprising (a) a polymeric carrier comprising a first polymer and (b) drug loaded

nanoparticles dispersed within said polymeric carrier, said drug loaded nanoparticles comprising: silicate particles comprising a layered silicate material; and a first therapeutic agent, wherein the first therapeutic agent is structurally associated with the silicate particles in that the first therapeutic agent occupies spaces between adjacent layers of the silicate material of each silicate particle to form a depot for the first therapeutic agent.

For a reference to anticipate a claim it must disclose each and every element of the claim. *See* MPEP 2131 and cases cited therein, *especially Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (Fed. Cir. 1978). WEBER fails as an anticipatory reference because it fails to teach all of the claimed elements of the present invention within the four corners of the reference, *i.e.* WEBER does not teach the claimed drug loaded nanoparticles wherein the first therapeutic agent is structurally associated with the silicate particles in that the first therapeutic agent occupies inner spaces between adjacent layers of the silicate material of each silicate particle to form a depot for the first therapeutic agent. Further, WEBER does not teach the additional features described in the remaining claims.

In his Office Action, the Examiner asserts that WEBER discloses a medical article comprising a release region further comprising the polymeric carrier comprising a first polymer, the drug loaded nanoparticles dispersed within the polymeric carrier, the layered silicate material (phyllosilicate), the hydrophilic therapeutic agent, the hydrophobic polymer, the disposal over at least a portion of the article, coronary or peripheral vasculature implantable or insertable devices, catheters, antithrombotic agent, smectite silicate silicate material and methods (Claim 25). At first, such a laundry list of individual elements from WEBER seems to have some merit under this rejection. A closer examination, however, finds that the list cited by the Examiner is just, in fact, a list of isolated elements, wherein the sum of the parts does not combine to furnish the current invention.

WEBER provides a detailed description of nanotechnology and its use in the reinforcement of medical devices (page 4, lines 8-22); devices that incorporate magnetic components (page 5, line 24 – page 6, line15); structures formed by heating nanoparticles comprising a heat sensitive

thermoplastic material (page 6, lines 16-23); and medical devices where nanoparticles are provided as a tie-layer and not necessarily incorporated into or disposed relative to the matrix material, including the option of heat welding the structure (page 6, line 24- page 7, line12), to name a few examples. WEBER's use of nanotechnology to capitalize on properties such as strength enhancement and radiopacity (page 10, lines 16-23) are interesting and useful, but they do not teach or suggest the present invention. Even the mention of synthetic or smectite phyllosilicates (page 9, lines 3-21) is without reference as to how to structure a medical device as described in the current Claims or even any mention of the ability to create a structure in which the therapeutic agent is disposed in the interstices between adjacent layers of the layered silicate material.

In fact, there is no instruction or enabling disclosure in WEBER for incorporating a therapeutic agent into a layered silicate material to create the claimed nanoparticle structure, i.e., a structure in which the therapeutic agent is disposed in the interstices between adjacent layers of the layered silicate material. In contrast to WEBER, the current specification teaches the benefit of such a structure: "By associating the therapeutic agent with the silicate particles, each silicate particle becomes a miniature depot for the therapeutic agent." (See current specification at paragraph 32). WEBER simply does not teach such claimed structure nor even suggest the benefit of such structure.

Thus, WEBER does not teach all of the elements of the Claims of the present invention; reconsideration and withdrawal the rejection under § 102(a) over WEBER is requested.

Rejection Under 35 U.S.C. §103(a)

The Examiner has rejected Claims 1 and 3 as being unpatentable over WEBER in view of Hunter et al. (U.S. Application Publication No. US 2005/0149175) ("HUNTER"). This rejection is respectfully traversed.

Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *In re Kahn,* 441 F.3d 977, 988 (Fed. Cir. 2006), *cited with approval in, KSR Int'l v. Teleflex, Inc.*, 127 S. Ct. 1727, 1740-41, 82 USPQ 1385, 1396 (2007).

As explained below, none of the references alone or in combination provides any reason or suggestion to combine the references to arrive at the present invention. *In re Nilssen*, 851 F2d. 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988).

The Examiner states that WEBER teaches a medical article comprising a release region and the disclosed article comprises the polyolefin-polyvinylaromatic block copolymer of instant claim 3. The Examiner states that WEBER differs from the instant application in that it does not teach halofuginone as a therapeutic agent, but the Examiner uses HUNTER to support the point that halofuginone as a therapeutic agent in vascular medical devices was well known in the art at the time the instant application was filed.

This rejection is traversed, in part, for the reasons described above for WEBER. In addition, the defects in WEBER are not remedied by the citation of HUNTER. HUNTER does not teach or even mention the use of nanoparticles and the Examiner's position that one skilled in the art would combine these two references is unsustainable. Even more importantly, HUNTER describes the use of intravascular devices that promote fibrosis between the devices and the host tissue. This is not the focus of WEBER or the present invention, and the promotion of fibrosis actually teaches away from combining these references.

Finally, neither WEBER nor HUNTER teaches or suggests any type of structure for drug loaded nanoparticles made of a layered silicate material and a therapeutic agent. As discussed above, WEBER provides no teaching or suggestion for the claimed nanoparticle structure. HUNTER provides no discussion or disclosure of nanoparticles whatsoever and thus, fails to address any deficiency in WEBER. As the combination of WEBER and HUNTER fails to meet the threshold for establishing a *prima facie* case of obviousness, the Examiner is respectfully requested to reconsider and to withdraw the rejection under 35 U.S.C. §103(a) based on WEBER in view of HUNTER.

Conclusion

In view of the foregoing, it is believed that the application is now in condition for allowance. Reconsideration of Claims 1-3, 19, 21-23, 25, 27 and 28 and early passage of this case

to issue is respectfully requested. If the Examiner believes there are still unresolved issues, a telephone call to the undersigned would be welcomed.

Respectfully submitted,

Dated: February 25, 2009

/Rosemary M. Miano/
Rosemary M. Miano
Registration No. 29,674

Attorney for Applicant
Mayer & Williams PC
251 North Avenue West, 2nd Floor
Westfield, NJ 07090
(908) 518-7700 Tel.
(908) 518-7795 Fax